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ABSTRACT

This paper reviews the problems of identifying the kinds of risks to which subjects in research projects are exposed, establishes the role of federal funding agencies in risk identification and suggests ways to protect children who are research subjects. The risks cited are primarily psychological, sociological, physiological, and/or academic. Examples of risks are overtesting of children, creating dependency, and labelling. A process for protecting human subjects from harm in research should be established at each institution receiving research funds. The researchers, possibly aided by a local committee, should be responsible for seeing that children who are research subjects are not at risk. The protection of children as research subjects is a complex effort requiring the participation of many groups and organizations at the federal, institutional, association and research project levels. (CH)

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The Role of Federal Funding Agencies in the Protection of Children as Research Subjects

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Federal Concerns

Children are harmed in all kinds of ways in our nation, ways which have nothing to do with research. They are harmed by accidents, abuse, drugs, corporal punishment, poor nutrition, air and water pollution, violence in mass media, neglect, poor housing, poor education, and a host of other things absent or present in their lives. Draw attention to the facts about what harms children and a few regulations are established. Toys are to meet safety standards. Seat belts or safety chairs are to be used. Air and water quality are to meet certain standards. The viewing of violence is to be curbed. Access to better education is mandated. Cases of child abuse and neglect are to be reported. Corporal punishment is to be witnessed. Access to housing and better nutrition is formulated. In short, our society has identified many things that harm children and has taken various steps to prevent such

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harm. These steps may be taken by citizen organizations, professional groups, private industry, governmental agencies or by legislative bodies. The value or appropriateness of the steps taken or, indeed, the effectiveness of the standards and regulations provided, are not of concern here. What is of concern is the fact that addressing problems of harm to children and providing ways to remove the harm is complex and difficult. Who knows for sure when a toy becomes harmful? Who knows for sure when a child is negatively affected by viewing violence? Clear cut cases of lead in paint on toys, a child abandoned and alone for ten days, a child imitating violence viewed on TV, are easy to recognize as harmful. But cases are seldom that clear cut and become less so as psychological and sociological harm is involved.

Using children as subjects for research illustrates the same concern of society, the issue of the range of harm, and the difficulty of establishing guidelines to prevent harm. Children react differently to experimental interventions, new programs, or change of any kind. What is joy to one child may be terror to another. What is seen as a great experience to one child may be seen as a devastating experience by another child. Some children, for example, thrive under highly structured educational programs while others feel frustrated, hemmed in and prevented from creative expression. The concern that society has for preventing harm to children is certainly

tempered by the variability of children's reactions to experimental experiences. The clear cut harm inflicted by certain drugs, certain instruments, certain shocks present no problem in prohibition of use. But, again what are the limits of harm, the range of harm, the individual differences in experiencing harm? These are difficult to identify and usually left to the judgment of select people.

The problem of establishing guidelines begins with trying to define what it means to say a person is at risk within a research project. The definition of "subject at risk" is incorporated in the Department of Health, Education, and Welfare regulations of May, 1974 on the Protection of Human Subjects involved in grants and contracts supporting research, development and related activities. Section 46.103(b) of the regulations defines "subject at risk" as "any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service". That kind of definition requires interpretation and the Secretary of DHEW provided interpretation in a published statement in the June 28, 1976 Federal Register.

This interpretation related specifically to welfare recipients, but in fact becomes an interpretation of the definition of "subjects at risk". The interpretation is quoted directly from the Federal Register:

> . . . . . .
>
> the regulations were not, and have never been, intended to protect individuals against the effects of research and development activities directed at social or economic changes, even though those changes might have an impact upon the individual. More particularly, they were not designed to protect against possible financial injury, which may result from alteration in the price, availability, or conditions of eligibility for benefits or services offered under a governmental program.

The interpretation provides more examples of such research and then goes on to interpret the standard for measuring any departure from "established and accepted methods".

> The standard for measuring any departure from "established and accepted methods" with respect to activities designed to test the effect of social and economic change has traditionally been intended by the Department to include the range of experience of the average American in his daily life. Thus, with respect to work requirements for able-bodied welfare recipients, the standard for determining such a departure would be the experience of the average able-bodied American who must work to obtain his sustenance rather than the experience of most welfare recipients who do not work. Similarly, subjecting a group of people to a requirement that they report income for purposes of obtaining governmental benefits, or causing a lowering of their income, or requiring them to make some payment toward the cost of their medical care would not depart from the normal

experiences which other Americans can expect to encounter in their daily lives, and would thus not constitute the type of departure from "ordinary and accepted methods" to which the regulations were intended to apply.

Moreover, the regulations are not intended to protect individuals from the "ordinary risks of daily life." There are certain risks which may reasonably be expected to be encountered by anyone, for example, the risks inherent in having to make a decision as to how to allocate funds, or in deciding whether to meet certain conditions, such as performing work, which are required in order to obtain funds. The exposure to the risks which emanate from these choices does not constitute the type of situation against which the Department's regulations are designed to guard.

Institutional Responsibility

What is important about these interpretations is not so much that the Secretary is making them, but that institutions receiving Federal grants and contracts are also interpreting the definitions. They cannot avoid doing so since each institution is required to address the problem. The 1974 regulations require that a review committee or group be established in each institution submitting a proposal for Federal funding of research. This committee or group is charged with the responsibility of reviewing the proposals to be submitted to determine if there are "subjects at risk". The committee must interpret the definition and make a decision. The institutions involved must fill out a form stating they have such a committee and must certify that each proposal has been

reviewed and a decision made about whether research subjects are at risk or not. The review process is what is mandated by the regulations. Nothing is mandated or even recommended when subjects are found to be at risk. It is not certain whether the research should not be supported, whether assurances of protection from harm are needed, whether Federal project officers should monitor for potential harm. None of this is clear nor is it clear where the burden of responsibility lies. I have seen letters from government officials which give completely different statements about the locus of responsibility and some law suits suggest the issue is neither clear nor resolved. The May, 1974, Regulations provide general authority to the head of a Federal executive unit to issue regulations for each unit, but these have not appeared in any public form, if they indeed exist. Most units are trying to meet the review process and certification requirements of the May, 1974 Regulations. The problem of regulations for children as research subjects is still not resolved after several years of addressing it.

The National Commission

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established by the National Research Act (P.L. 93-348) and has provided leadership for stating policies and guidelines which

become regulations to assure the protection of research subjects. Their work to date has been primarily with DHEW, although there is much evidence that their responsibility is to be widened to include all Federal executive departments. The two questions the Commission asks of DHEW components are these:

> Does your component of DHEW or any element thereof conduct or support any biomedical or behavioral research involving human subjects?
>
> If such research is conducted or supported, what policies and procedures are enforced to assure the protection of human subjects?

These questions provided the basis for the May, 1974 Regulations and may soon be asked of Departments other than HEW. The Commission has had great difficulty addressing the problem of children as research subjects. In the Commission's May 6, 1976 Preliminary Draft of Children as Research Subjects, the following summary of the history and present status of the problem is stated:

> In 1964, the World Medical Association published its code of research ethics, the Declaration of Helsinki, which provides that "if (the subject) is legally incompetent the consent of the legal guardian should be secured". The Helsinki code was adopted in this country by the Society for Clinical Investigation, the American College of

Physicians, the American College of Surgeons, and most importantly, the American Medical Association, thus providing support for the general acceptance of proxy consent for the participation of children in research.

The Institutional Guide to DHEW Policy for the Protection of Human Subjects, published in 1971, endorsed the Helsinki code and provided for the consent of an "authorized representative of a subject who could not provide his or her own legally valid consent. The 1971 policy was converted into Federal regulation in May, 1974, more or less as originally written, except that the current regulations require that anyone consenting on behalf of another be a "legally authorized representative". This is defined in the regulations as "an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject's participation in the particular activity or procedures". In November, 1973, the Department proposed additional policy for the protection of children as research subjects, including a provision for the consent or agreement of children age 7 or over; however, the proposals have not been developed into rulemaking, as yet.

The problems are both legal and ethical. What are the legal rights of children in consenting to participate in research? What are their legal rights when the research is therapeutic and when it is non-therapeutic for the particular child? What moral responsibility does a child have to be used as an instrument to provide empirical evidence necessary to the expansion and validation of human knowledge? What is the role of parental consent? Who can speak for institutionalized and incompetent children?

Answers to these questions vary greatly, as the

Commission learned from its April 9, 1976, public hearing on the issue of research involving children. Some experts stated a child should give consent at age 7. Others scoffed at this as reflecting naive notions about generalizable abilities of seven year olds. Some stated that in therapeutic research the child's consent should not be necessary while others felt the child should be able to give consent. Some stated that the individual rights of children take precedence over social obligations while others stated exactly the opposite view. Some experts stated that no institutionalized minors should be research subjects while others stated that, with proper third party approval, such subjects should be part of research. The whole notion of informed consent was raised with no clear answers. One expert made four comments about informed consent which highlighted the problems: (1) it has many levels of meaning for different kinds of children; (2) it is a continuing process and not a one time affair; (3) it is improper and meaningless to propose an age at which a child may give informed consent, since there can be no single criteria; and (4) we must question the purpose of informed consent.

Professional Associations

The Commission is not the only group having problems with the legal and ethical aspects of children as research subjects. The professional organizations such as APA, AMA, AERA, NEA

also are confronted and confounded by these problems. Each of these organizations has standards of ethics, but none, to my knowledge, participated in the development of the May 1974 DHEW Regulations, nor am I aware of any that has studied the Regulations in terms of the professional standards and ethics, and reacted to the DHEW Regulation. I have attended numerous meetings where representatives from the professional organizations have decried the issuance of the Regulations without their involvement, but I am not aware of any formal action on the part of the organizations.

Where are we, then, in this entire issue of children as research subjects? We have the DHEW Regulations which include children. These regulations are primarily to establish a process of review of proposals at the institution generating level to certify that a review has taken place and a decision made about the risk to subjects. Interpretations of the Regulations are being made at the Federal level and will probably continue to be made. These interpretations will affect researchers. We have statements of ethics and professional behavior from organizations whose members conduct research. Neither the statements nor the organizations seem to be coming to grips with the implications of the Federal Regulations. We have some legal court cases concerning parental consent, which have ruled differently,

depending on the different cases. We have no clear or generally accepted views or recommendations concerning the issue of children as research subjects, nor do I, for one, believe such generally accepted views and recommendations are possible or even desirable. Children are different. Research is different. Locations are different. Attitudes are different. Risk is different. But before it appears I am moving toward no views or recommendations, let me hasten to assure you I feel there is a way to address this complex issue. Let me illustrate with research involving children supported by several Federal funding agencies and in which an accumulation of experience identifying risk has emerged. Then, I will present a design to protect children, which includes the design framework and the critical participants in carrying out the obligation to protect children in research.

Federal Agencies Identify Risks

Federal funding agencies are in a position to learn a great deal about the kinds of research risks children experience. The Agencies acquire this information through being familiar with thousands of projects involving children, monitoring these projects, and sharing experiences. In short, the funding agencies accumulate a vast amount of information about various kinds of risks to children which are not

identified in the Regulations or by organizations. Many of these risks appear in preschool and school settings where much research is conducted. Children who are in preschool and school centers or classrooms are a captive audience who are seen as highly desirable as research subjects. Their attendance is pretty good, their availability almost assured and the population sampling quite general. A good deal of research depends completely on these captive audiences. Parental consent is required for the conducting of research in preschool or school settings, but this is obtained in different ways at different times and by different researchers or institutions. Informed parental consent, however, raises all kinds of questions about what information is needed, how much, with what degree of understanding, etc.? But, let's assume the appropriate consent has been provided. The paramount question then becomes: What are the risks to research subjects in preschool and school centers or classrooms? The risks may be psychological, sociological, physiological and/or academic. These risks are presented and discussed, followed by a statement on how to protect children who are research subjects at risk.

1. Overtesting. Many children are tested for too long a time at one session or over too much time. Their physical limitations may be

ignored and they may be reluctant to complain of fatigue because they are part of a study. The overtesting is frequently tied in with the desire of the researcher to validate and standardize tests and to take advantage of an available population which is part of a research project.

2. Labelling. While it is necesseary to give names to conditions and diagnoses, it is not necessary or accurate to stereotype behavior from labels. Children from minority groups and families with low incomes are particularly likely to be stereotyped and stigmatized. Also, children labelled as mentally handicapped may easily be stereotyped and stigmatized.

3. Creating dependency. Some research provides services to children which encourages dependency on the providers. This may be either an integral or peripheral part of the research. It may even be a desired outcome, but what happens when the research ends? Not all researchers address this problem.

4. Expecting or forcing continued participation. Many children are fearful of withdrawing from the project. They like to keep their commitment

and do not like to be different from the children who stay in the research project. They also feel guilty. These feelings may prevent them from withdrawing even when they are disturbed by the project or have nightmares about it.

5. Misuse of findings. The misuse of research findings takes many forms; one is omission and the other commission. The misuse of omission occurs when the lack of feedback on the research findings leaves the involved subjects anxious about the outcome or unable to benefit from the findings. The misuse of commission occurs when findings are made available selectively to support prejudices or when findings are made available without respect for the privacy rights of the subjects.

6. Overuse as research subjects. Many children, particularly those who meet low income and underachievement criteria, are placed in so many research projects that they are isolated from the school's mainstream, both academic and social, and have problems with re-entry into the mainstream. There are few records of the scope, both in numbers of research programs and

years of such programs, to determine the potential harm or indeed, the accrued benefits.

7. Unidentified or unusual treatment. Some researchers do not want children to know about the treatment or technique being used in a research project. This is especially true in behavior modification techniques which relie on an unawareness on the part of the subject. Unusual treatment may include techniques or subject matter that exposes children to moral and cultural shock.

8. Inappropriate questions. Even if research findings are not misused, there are many questions which are inappropriate. These questions include those asking about peer and family relationships, one's sense of failure or success, one's experiences with drugs or delinquency. As a matter of fact, recent research involving self-reports of youth were terminated because youth were in fact being asked to provide self-incriminating information.

9. Attitudes of researchers. There are researchers who feel their commitment to generating knowledge

should take precedence over concern for the effects of the research on the subjects. They want the data, and they do not want any contamination of the data by loss of subjects, restrictions in procedures, involvement of subjects in data use, etc. There are other researchers who already hold biases and prejudices about certain populations and conduct their research to, in fact, support the biases and prejudices.

10. Dangerous treatment. The use of electric shock, drugs, psychological and other biomedical techniques in research with children in preschool and school settings has already brought many responses from the public. These responses are usually accompanied by evidence of damage. The Secretary's interpretation of "Subject at Risk" referred to above, incorporates the special concern for dangerous treatment.

The types of risk situations against which the regulations were designed to protect are suggested by the areas of concern which were addressed in the legislative hearings held in conjunction with the enactment of section 474 U.S.C. 2891-3 (added by

> Pub. L. No. 93-348), which forms part of the basis for the Departmental regulations at 45 CFR Part 46, and in the preambles to the proposed and final regulations at 45 CFR Part 46. The subjects addressed included the use of FDA-approved drugs for any unapproved purpose; psycho-surgery and other techniques for behavior control currently being developed in research centers across the nation; use of experimental intrauterine devices; biomedical research in prison systems and the effect of that research on the prison social structure; the Tuskegee Syphilis Study; the development of special procedures for the use of incompetents or prisoners in biomedical research; and experimentation with fetuses, pregnant women, and human in vitro fertilization. The regulations were intended, and have been uniformly applied by the Department, to protect human subjects against the types of risks inherent in these types of activities.

The interpretation is broader than for children alone, but certainly includes them.

A design to protect Children

There are many participants in a design to protect children as research subjects and each participant has many roles, some individual and some in coordination with other participants. Let me attempts to describe the design and the role of the participants. The design consists of regulations, laws, children's rights, kinds of risks, responsibility and accountability. The participants are

the National Commission for the Protection of Human Subjects, the Federal DHEW, the funding agencies, the professional associations, the research institutions, the research subjects, (and parents) and the researchers.

While no hard and fast design is functional or appropriate, the one presented here may form a schema or model for protecting children at research risk.

A major function of the Commission is to continue providing guidelines to the nation to assure that a process for protecting human subjects from harm in research is established at each institution receiving research funds. This process should continue to include the certification of each project submitted for funding by that institution.

A function of DHEW is to interpret the May 1974 regulations as issues are raised or as seems needed. However, the professional associations in the nation which have standards and ethics to guide the researchers among their membership, should also be interpreting the 1974 Regulations. And they should go further, they should examine their standards and ethics in light of the regulations and decide if they need to change their standards and ethics. Do the standards or ethics define subjects at risk? Do they include a statement on age of child consent and the content of informed consent? Or they may decide they should make a strong case against all or parts of the 1974

Regulations. This dialogue or interaction has rarely taken place and when it has, the atmosphere is frequently one of resentment against the Regulations or fear of loss of freedom to conduct research.

One function of the funding agency is to continue to accumulate information on various kinds of research risk. Another function is to assure that each project funded has been reviewed and certified at the institution from which the research came. If subjects are at risk, as stated by the review process, or are perceived to be at risk by the funding agency, careful monitoring is necessary to assure no harm is done subjects at risk. OCD has addressed this problem by asking the OCD Committee of outside research experts to examine each project to determine if there are subjects at risk and if sufficient safeguards are present. If there are questions, the institution is contacted by OCD to receive further evidence of safeguards. The project officers, OCD professional staff members, for all funded projects also look at projects assigned to them for monitoring. If at any time over the life of the project, they feel children are at risk without sufficient safeguards, they bring this information to a standing committee within OCD, for discussion and plan of action. If action is needed, the project officer relays the recommendation to the researcher on the funded project for

discussion of actions needed.

The research institution which provides the process for reviewing proposals to determine if subjects are at risk have no clear cut plan to monitor projects which indeed have subjects at risk. They have no guidelines other than what they provide on an ad hoc basis for determining what is an appropriate safeguard. Further, there is no plan for monitoring the project to assure that no harm is possible. Once the certification for the project is made by the institution, the involvement need not and usually does not continue. Accountability is involved and this poses legal liability questions.

The researchers are entitled to the support and protection available to them from their institutions, their professional organizations, and the federal funding agencies. The researchers are responsible for conducting their research and are accountable to the agencies, institutions and associations. But these are usually too removed for every day carrying out of the research. The researcher must know continuously whether subjects are at risk, whether informed consent is accurate, whether the more subtle dangers identified earlier in this paper are present or likely to occur. And to help the researchers on this day by day work, it seems desirable for them to have a small committee to discuss problems with, to report to, and to be immediately

accountable to. The committee could be comprised of a member of the institution review group, a member of the substantive field and a member of the community or population from which the research subjects are selected.

It seems highly desirable for professional associations to play a key role in describing what the functions and purpose of such a Committee would be to assure the protection of children in research. The institutions are not organized to develop this among themselves and the Federal agencies are too far removed. But the crucial place for protecting children in research is where the research is taking place on a day to day basis. There is no time to write to the Commission, HEW or perhaps even to convene the institution review committee. But the researchers need immediate help both to carry out their research responsibility and to be accountable to others. The issue of legal liability will need to enter the discussion at some point, but that is something the professional associations can address.

Summary and Conclusions

Our concerns for children include risks to them as with all human beings and risks to them as children. Guidelines, regulations and procedures are provided from many sources to help protect children who might be or are research subjects at risk. The specific protections of children have

not been spelled out in any official documents other than a requirement of informed parental consent to permit a child to participate in research. The rights of the children independent of others, including parents, are not stated in any policy form.

Research practice that is particularly harmful to children, and that can be pointed out by funding agencies, includes not only drugs, electric shock, and certain biomedical techniques, but also includes overtesting, labelling, misuse of findings, attitudes of researchers, culture and moral shock, dependency on researcher, etc.

The protection of children as research subjects is a complex effort requiring the participation of many groups and organizations at the federal, institutional, association and research project levels. A model for relating the efforts of the participants and assigning tasks and responsibilities is presented. In the final analysis, the child in an ongoing research project is of paramount concern, and the responsibility and accountability of the researcher conducting the project is immediate. To help the researcher and protect the child, a local committee is recommended to act as a sounding board, to assure protection of the research subjects, and to hold the research to responsible and accountable performance.